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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/030,497 | 06/27/2002 | John C. Reed | P-LJ 5137 | 2174 |
| 41552 | 7590 | 01/23/2007 | EXAMINER | |
| MCDERMOTT, WILL & EMERY 4370 LA JOLLA VILLAGE DRIVE, SUITE 700 SAN DIEGO, CA 92122 | | | SANG, HONG | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1643 | |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 01/23/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/030,497 | REED, JOHN C. |
| | Examiner | Art Unit |
| | Hong Sang | 1643 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 November 2006.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 89-117 is/are pending in the application.
 4a) Of the above claim(s) 111-113 and 115-117 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 89-110 and 114 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____.
 5) Notice of Informal Patent Application
 6) Other: _____.

DETAILED ACTION

RE: Reed

1. Applicant's response filed on 11/17/2006 is acknowledged. Claims 89-117 are pending. Claims 1-88 are cancelled. New claims 110-117 are added.
2. Due to species election of BAG-1 (see applicant's response filed on 9/23/05), claims 111-113 and 115-117 are withdrawn from consideration as being drawn to non-elected inventions.
3. Claims 89-110, and 114 are under examination. Claims are examined to the extent that BAG-1 gene encodes BAG-1.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

5. The rejection of claims 89-109 and new claims 110 and 114 under 35 U.S.C. 103(a) as being unpatentable over Froesch et al. (Proceedings of the American Association for Cancer Research Annual Meeting, March, 1998, 89: 13, print) in view of the teachings of Takayama et al. (Cancer Research 1998, 58: 3116-3131, IDS), Noordzij et al. (J. Urology, 1997, 158: 1880-1885) and Sano et al. (US patent NO. 5,665,539, IDS) is maintained.

The response states that none of the reference provides teaching or suggestion that the level of BAG-1 gene expression can be used to determine the risk of tumor recurrence or spread or for determining prognosis of survival in a patient suffering from

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prostate cancer by determining BAG-1 gene expression. The response states that Froesch et al. describes the observation that BAG-1L is expressed in prostate cancers and enhances androgen receptor function. The response states that Takayama et al, indicates that breast, colon and leukemia cell lines had consistently higher relative levels of 36-kDa BAG-1 protein expression but provides no teaching or suggestion that BAG- 1 expression can be used for determining the risk of tumor recurrence or spread or for determining prognosis of survival in a patient suffering from prostate cancer. The response states there is no motivation to combine the cited references. The response states that there would have been no reasonable expectation of success to combine the reference.

Applicant's arguments have been carefully considered but are not found persuasive. Froesch et al. teach that BAG-1 protein (cytosolic BAG protein) is expressed in all 9/9 prostate cancer cell lines and 51/51 archival prostate tumor specimens (see abstract and title). Takayama et al. teach that overexpression of BAG-1 has been shown to increase the metastatic potential of tumor cells *in vivo* (see page 3116, right column, 2nd paragraph, lines 5-7). Takayama et al. teach that BAG-1 can promote cell survival and augment the bioactivities of several proteins known to be important for tumorigenesis (e.g. bcl-2, Raf-1, HGF-R, and PDGF-R) (see page 3117, left column, 3rd paragraph). Takayama et al. teach that BAG-1 can be regarded as a candidate proto-oncogene (see page 3117, left column, 3rd paragraph). Takayama et al. teach that BAG-1 protein is consistently the most abundant form of BAG-1 expressed in tumors (see page 3127, left column, 1st paragraph). Therefore, in view of the

teachings of Froesch and Takayama, one of ordinary skill of art would reasonable conclude that the presence of BAG-1 protein is correlated with the metastatic potential of tumor cells and BAG-1 will promote the cancer cell survival. While Froesch and Takayama do not specifically describe comparing the level of BAG-1 protein in cancer cells to a reference level, because Takayama et al. teach that overexpression of BAG-1 protein increases the metastatic potential of tumor cells, one of ordinary skill of the art would understand that "overexpression" indicates the expression level is above a reference level or a normal level. Because the only active steps of claim 1 is determining a BAG-1 gene expression level in prostate cancer tissue, and comparing said BAG-1 gene expression level to a reference level, said BAG-1 gene expression level above the reference level correlates with an increased risk of tumor recurrence, below the reference level correlates with an decrease risk of tumor recurrence, Froesch and Takayama et al. teach all the limitations of claim 1.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to determine the level of BAG-1 expressed in prostate cancer using immuno-PCR, compare the level with a reference level and further correlate the results with the risk of tumor recurrence, tumor spread and survival in a patient suffering from prostate cancer in view of the teachings of Froesch, Takayama, Noordzij and Sano. One would have been motivated to do so because Froesch et al. teach that BAG-1 protein is expressed in all 9/9 prostate cancer cell lines and all 51/51 prostate tumor specimens, and Takayama teaches that overexpression of BAG-1 has been shown to increase the metastatic potential of tumor cells *in vivo* and

BAG-1 promotes cell survival. Moreover, one of ordinary skill in the art would have had a reasonable expectation of success to determine the level of BAG-1 protein expressed in prostate cancer using immuno-PCR, compare the level with a reference level and further correlate the results with the risk of tumor recurrence, tumor spread and survival in a patient suffering from prostate cancer because Froesch et al have already successfully detected BAG-1 protein in all 9/9 prostate cancer cell lines and all 51/51 prostate tumor specimens, and Takayama teaches that overexpression of BAG-1 has been shown to increase the metastatic potential of tumor cells *in vivo*, and BAG-1 protein promotes cell survival. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. Because of these reasons, the rejection is maintained.

Conclusion

6. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hong Sang, Ph.D.
Art Unit 1643
Jan.5, 2007


CHRISTOPHER H. YAEN
PRIMARY EXAMINER